



John D. Thallemer
Senior Patent Attorney
Novartis Corp. Intellectual
Property

Sandoz, Inc.
506 Carnegie Center, Suite 400
Princeton NJ 08540-6243

Tel (609) 627-8507
Fax (609) 627-8636
Internet: john.thallemer
@novartis.com

August 16, 2006

Daniel Stemmer
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Re: Case BP/G-32574A/BCK, U.S. Serial # 10/520,569

Dear Mr. Stemmer:

Attached herewith is an executed declaration provided by Michael Betz for submission to the USPTO.

Also included with this cover letter is an executed declaration provided by John Stevens (previously sent to you with missing parts), and a copy of your Decision letter.

Please feel free to call me in case you have any questions.

Very truly yours,

A handwritten signature in cursive script that reads 'John Thallemer'.

John D. Thallemer

34,940

JDT: RD

Serial pages = 10

RECEIVED

17 AUG 2006

Legal Staff
International Division

US Case BP/G -32574A/BCK

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION☒ Original☐ Supplemental☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

the specification of which:

☐ is attached hereto.☐ was filed on _____ as Application No. _____
(day/month/year)and, if this box (☐) contains an *☐ was amended on _____
(day/month/year)☒ was filed as Patent Cooperation Treaty International Application No.PCT/EP03/07347 on 08/07/2003
(day/month/year)and, if this box (☐) contains an *☐ entered the national stage in the United States and was accorded Application No. _____and, if this box (☐) contains an *☐ was amended, subsequent to entry into the national stage, on _____
(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty International application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty International filing date of the continuation-in-part application.

US Case BP/G -32574A/BCK

I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED	
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No
			<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)
60/394,612	09/07/2002
60/394,699	09/07/2002
60/394,611	09/07/2002

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date (day/month/year)
----------------------------------	--	--	--

US Case BP/G -32574A/BCK

I hereby appoint all of the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box (☐) contains an x ☒, I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole
or first joint inventor

Michael BETZ

Inventor's signature



Date

11.08.2006
(day/month/year)

Residence

8200 Schaffhausen

Citizenship

citizen of Germany

Post Office Address

Jägerstrasse 1
8200 Schaffhausen
Switzerland

Full name of second
joint inventor, if any

John STEVENS

Inventor's signature

Date

(day/month/year)

Residence

Thornton Heath, CR7 7LP, Great Britain

Citizenship

citizen of Great Britain

Post Office Address

J.D.S. Consulting
18 Woodland Rd, Thornton Heath,
CR7 7LP, Great Britain

IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.

US Case BP/G -32574A/BCK

DECLARATION AND POWER OF ATTORNEY FOR UNITED STATES PATENT APPLICATION☒ Original ☐ Supplemental ☐ Substitute

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name, and

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if more than one name is listed below) of the subject matter which is claimed and for which a United States patent is sought on the invention entitled

LIQUID FORMULATIONS WITH HIGH CONCENTRATION OF HUMAN GROWTH HORMONE (HGH) COMPRISING PHENOL

the specification of which:

☐ is attached hereto.☐ was filed on _____ as Application No. _____
(day/month/year)and, if this box (☐) contains an *☐ was amended on _____
(day/month/year)☒ was filed as Patent Cooperation Treaty international Application No.PCT/EP03/07347 on 08/07/2003
(day/month/year)and, if this box (☐) contains an *☐ entered the national stage in the United States and was accorded Application No. _____and, if this box (☐) contains an *☐ was amended, subsequent to entry into the national stage, on _____
(day/month/year)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment(s) specifically referred to above and, if this application was filed as a Patent Cooperation Treaty international application, by any amendments made during the international stage (including any made under Patent Cooperation Treaty Rule 91, Article 19 and Article 34).

I acknowledge my duty to disclose information which is material to patentability as defined in 37 C.F.R. 1.56, including, for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or Patent Cooperation Treaty international filing date of the continuation-in-part application.

US Case BP/G -32574A/BCK

I hereby claim the benefit under 35 U.S.C. 119(a)-(d) or (f) or 365(b) of any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate listed below and under 35 U.S.C. 365(a) of any Patent Cooperation Treaty international application(s) designating at least one country other than the United States listed below and have also listed below any foreign application(s) for patent, inventor's certificate or plant breeder's right certificate and Patent Cooperation Treaty international application(s) designating at least one country other than the United States for the same subject matter and having a filing date before that of the application the priority of which is claimed for that subject matter:

COUNTRY/REGION (OR P.C.T.)	APPLICATION No.	FILING DATE (day/month/year)	PRIORITY CLAIMED
-------------------------------	-----------------	---------------------------------	------------------

<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No
<input type="checkbox"/> Yes	<input type="checkbox"/> No

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below:

APPLICATION NO.	FILING DATE (day/month/year)
-----------------	---------------------------------

60/394,612	09/07/2002
60/394,699	09/07/2002
60/394,611	09/07/2002

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s) listed below and under 35 U.S.C. 365(c) of any Patent Cooperation Treaty international application(s) designating the United States listed below:

United States Application No.	United States Filing Date (day/month/year)	Status (Pending, Abandoned or U.S. Patent No.)	International Application No. and Filing Date (day/month/year)
----------------------------------	--	--	--

US Case BP/G -32574A/BCK

I hereby appoint all of the registered practitioners associated with Customer No. 001095, respectively and individually, as my attorneys and agents, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

If this box (☐) contains an x ☒, I hereby authorize the registered practitioners associated with Customer No. 001095 and any others acting on my behalf to take any action relating to this application based on communications from Corporate Intellectual Property of Novartis International AG, Basle, Switzerland, or an affiliate thereof or a successor thereto, without direct communication from me.

Please send all correspondence relating to this application to the address associated with Customer No. 001095.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Full name of sole
or first joint inventor

Michael BETZ

Inventor's signature

Date

(day/month/year)

Residence

8200 Schaffhausen

Citizenship

citizen of Germany

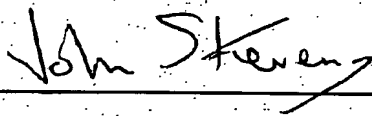
Post Office Address

**Jägerstrasse 1
8200 Schaffhausen
Switzerland**

Full name of second
joint inventor, if any

John STEVENS

Inventor's signature



Date

1/1/05

(day/month/year)

Residence

Thornton Heath, CR7 7LP, Great Britain

Citizenship

citizen of Great Britain

Post Office Address

**J.D.S. Consulting
18 Woodland Rd, Thornton Heath,
CR7 7LP, Great Britain**

IMPORTANT: Before this declaration is signed, the patent application (the specification, the claims and this declaration) must be read and understood by each person signing it, and no changes may be made in the application after this declaration has been signed.



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

15 FEB 2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER NJ 07936-1080

JDT



In re Application of
BETZ et al.

Application No.: 10/520,569

PCT No.: PCT/EP03/07347

Int. Filing Date: 08 July 2003

Priority Date: 09 July 2002

Attorney Docket No.: BP/G-32574A/BCK

For: LIQUID FORMULATION WITH HIGH
CONCENTRATION OF HUMAN GROWTH HORMONE
(HGH) COMPRISING 1,2- PROPYLENE PHENOL

DECISION

This is a decision on applicants' petition under 37 CFR 1.47(a) filed 29 November 2005 in the United States Patent and Trademark Office (USPTO).

BACKGROUND

On 08 July 2003, applicants filed international application PCT/EP03/07347, which designated the United States and claimed a priority date of 09 July 2002. A copy of the international application was communicated from the International Bureau to the USPTO on 15 January 2004. The thirty-month period for paying the basic national fee in the United States expired at midnight on 10 January 2005 (09 January 2005 being a Sunday).

On 07 January 2005, applicants filed a submission for entry into the national stage in the United States which was accompanied by, *inter alia*, the U.S. Basic National Fee.

On 29 June 2005, the United States Designated/Elected Office (DO/EO/US) mailed a NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 (Form PCT/DO/EO/905) indicating, *inter alia*, that an oath or declaration of the inventors in compliance with 37 CFR 1.497(a)-(b) and the surcharge under 37 CFR 1492(e) for providing the oath or declaration later than thirty months from the priority date were required.

On 29 November 2005, applicants filed the instant petition under 37 CFR 1.47(a) which was accompanied by, *inter alia*, a declaration of the inventors, the surcharge under 37 CFR

FEB 23 2006
rec'd Y6

Application No.: 10/520,569

-2-

1.492(e) for providing the declaration of inventors later than thirty months from the priority date, a petition/fee for a three month extension of time, a copy of an untranslated letter from Dr. Peter Gasteiger to Dr. Michael Betz, and a copy of an untranslated letter from Dr. Michael Betz to Biljana Colovic.

On 30 November 2005, applicants filed English translations of the letters filed 29 November 2005.

DISCUSSION

A petition under 37 CFR 1.47(a) must be accompanied by: (1) the fee under 37 CFR 1.17(h); (2) factual proof that the missing joint inventor refuses to execute the application or cannot be reached after diligent effort; (3) a statement of the last known address of the missing inventor; and (4) an oath or declaration by each 37 CFR 1.47(a) applicant on his or her own behalf and on behalf of the non-signing joint inventor.

As to item (1), the petition fee of \$200 has been charged to Deposited Account 19-0134. Accordingly, item (1) has been met.

Items (2)-(4) have also been satisfied.

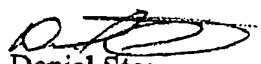
CONCLUSION

For the above reasons, applicants' renewed petition under 37 CFR 1.47(a) is GRANTED.

As provided in 37 CFR 1.47(a), a notice of the filing of this application will be forwarded to non-signing inventor at his last known address of record.

A notice of the filing of the application under 37 CFR 1.47(a) will be published in the Official Gazette.

This application is being forwarded to the National Stage Processing Branch of the Office of PCT Operations to continue national stage processing of the application, including the accordation of a 35 U.S.C. §§371(c)(1), (c)(2), and (c)(4) date of 29 November 2005.


Daniel Stemmer
Legal Examiner
PCT Legal Affairs
Office of Patent Cooperation Treaty
Legal Administration
Telephone: (571) 272-3301
Facsimile: (571) 273-0459



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

MICHAEL BETZ
JAGERSTRASSE 1
8200 SCHAFFHAUSEN
SWITZERLAND

In re Application of
BETZ et al.

Application No.: 10/520,569

PCT No.: PCT/EP03/07347

Int. Filing Date: 08 July 2003

Priority Date: 09 July 2002

Attorney Docket No.: BP/G-32574A/BCK

For: LIQUID FORMULATION WITH HIGH CONCENTRATION OF HUMAN GROWTH
HORMONE (HGH) COMPRISING 1,2- PROPYLENE PHENOL

Dear Mr. Betz:

You are named as an inventor in the above-captioned United States national stage application, filed under the provisions of 37 CFR 1.47(a) and 35 U.S.C. 116. Should a patent be granted, you will be designated as an inventor.

As a named inventor, you are entitled to inspect any paper in the file wrapper of the application, order copies of all or any part thereof (at a prepaid cost per 37 CFR 1.19) or to make your position of record in the application. Alternatively, you may arrange to do any of the preceding through a registered patent agent or attorney presenting written authorization from you. Joining in the application would entail the filing of an appropriate oath or declaration by you pursuant to 37 CFR 1.63.

A handwritten signature in dark ink, appearing to read "Daniel Stenmer".

Daniel Stenmer

PCT Legal Examiner

PCT Legal Affairs

Office of Patent Cooperation Treaty

Legal Administration

Telephone: (571) 272-3301

Facsimile: (571) 273-0459

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER NJ 07936-1080

*** RX REPORT ***

RECEPTION OK

TX/RX NO	6367
RECIPIENT ADDRESS	16096278636
DESTINATION ID	
ST. TIME	08/17 10:47
TIME USE	10'33
PGS.	10
RESULT	OK